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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

July 28, 1999

Cin WL-99-339

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Albert J. Cook, M.D.
Director of Radiology
Kent Mammography Center
401 Devon Place, Suite 111
Kent, OH 44240

Inspection I.D.#: 1649880004

Dear Dr.Cook:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected your facility on July 13, 1999. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

> Your system to communicate results is not adequate for the site: Kent Mammography Center. Your system does not include written communication to the patient concerning serious or highly suggestive malignancy cases within three to five working days of the mammography examinations.

The specific deficiency noted above appeared under the **Level 1** heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the **Level 2** noncompliance that was listed on the inspection report provided to you at the close of the inspection. This **Level 2** noncompliance is:

> Five of five random mammography reports reviewed by the inspector did not contain the required assessment category for the site: Kent Mammography Center.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

On or about July 26, 1999, you submitted to this office via facsimile your written response to the noncompliance items as noted above. Your letter indicated that your facility now has a written policy that your facility will mail to the patients with serious or highly suggestive malignancy cases as soon as possible, but no more than 5 days after the reports have been verified. Is your policy consistent with the requirement that the patient is notified in writing within five working days of the mammography examination?

Your July 26, 1999 letter adequately addressed the Level 2 and Level 3 noncompliance issues. Please indicate with your written response to the Level 1 noncompliance any additional comment, if any, regarding Level 2 and 3 noncompliance issues.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

Mr. R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097.

Also, please send a copy to the State radiation control office:

Ms. Teri Eckert
Ohio Department of Health
Northeast District Office
Oliver R. Ocasek Government Office Building
161 S. High St. Suite 400
Akron, OH 44308-1616

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,

Mary L Womack for

Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/TEckert